



Redesigning the drug distribution system in hospitals

EAHP's request for the introduction of single dose packed medicines

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Conflict of interest

Nothing to disclose

Agenda

- EAHP
- Definitions
- Brief history / past activities
- Who is supporting single dose
- Medication process in hospitals
- Why bar coded single dose in hospitals
- The statement by EAHP: an update



European Association of Hospital Pharmacists (EAHP)

- **Created in 1972 in The Hague (NL)**
- **Federation of National Associations of Pharmacists**
- **Members of the Council of Europe**
- **31 countries: 24 EU + 7 outside EU**
- **More than 21,000 Hospital Pharmacists working in hospitals and other healthcare facilities in Europe**

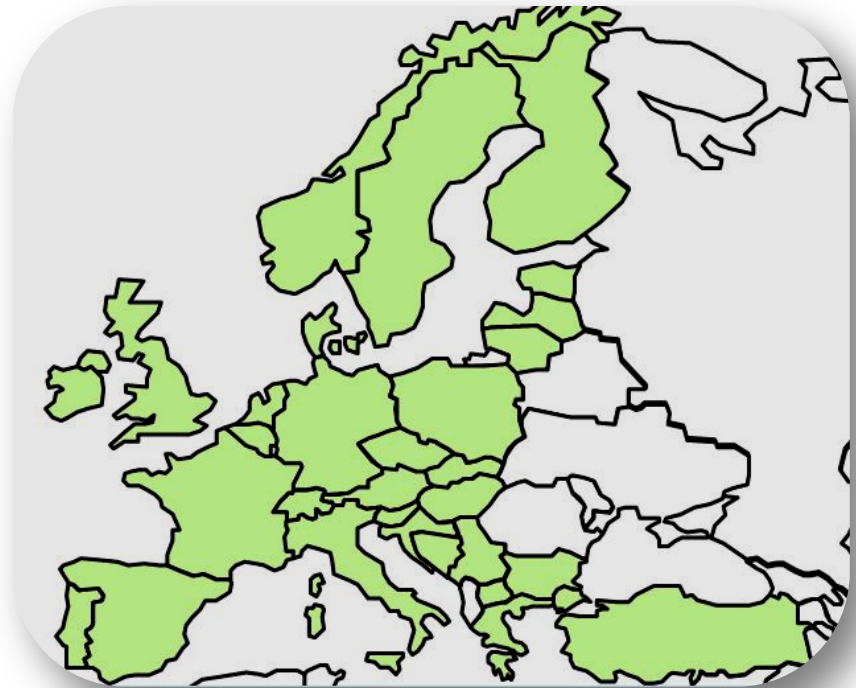


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31 members



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GS1 Health Conference Geneva 2010



Definitions



■ Multiple dose blister

- Package which fully encloses the drug.
- Each dosage form is individually packaged. The individually blistered identical dosage forms are attached to each other to one strip.
- The labelling is imprinted on the complete strip but not on the individual blistered dosage forms



Definitions

■ Unit dose package

- A unit dose package contains the particular dose of the drug for **a specific patient** according to the patient-specific prescription.
- Unit-dose packages are dispensed for one or several days by a centralized supply service unit and are labelled specifically for a patient.



Definitions

■ Single dose blister package

- Drug blister package for a single dose. A number of single doses might be attached to each other, but are easy to separate through a perforation.
- **Each single-dose is individually and fully labelled.**





History

- The General Assembly (GA) June 2006 decided to ask the board of director to promote single dose for medicines used in hospitals
- ⇒ Working group
 - Prof. Pascal Bonnabry, Switzerland
 - Dr. Steffen Amman, Germany
 - Sophie Verbeke, Belgium
 - Dr. Roberto Frontini, Germany
- Statement of EAHP after approval by the GA June 2007, update **2010**
- Press release April 2008 about the importance of single dose in terms of patient safety



Activities

- **September 2007, Brussels**

Meeting with EFPIA



Meeting with GIRPS (Wholesalers)



- **November 2008, Paris**

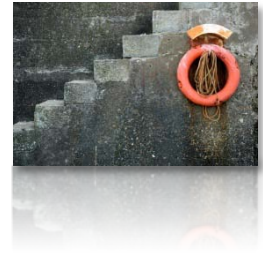
Meeting with Sanofi-Aventis

- **September 2009, Basel**

Meeting with Novartis



Who is supporting the Single Dose



■ European Commission

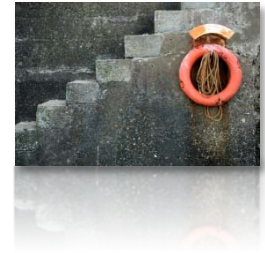
- “European guideline on the readability of the label and package leaflet of medicinal products for human use”
September 2006

Section C.1, “Blister pack packaging”:

*“Where a unit-dose blister presentation is proposed, all the information required for blister packs **must appear on each unit presentation**”.*



Who is supporting the Single Dose



■ Council of Europe

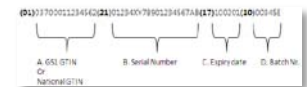
■ Report

"Creation of a better medication safety culture in Europe: Building up safe medication practices"

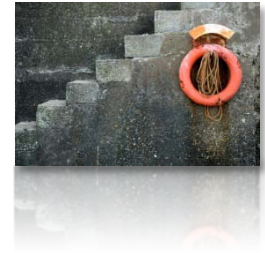
19th March 2007

■ EDQM Group Track and Trace Integration of Pharmacies

14th January 2010



Who is supporting the Single Dose



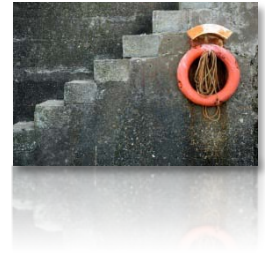
- FDA



- Since April 2006 in USA mandatory for all hospital products
- Guidance for Industry. Bar Code Label Requirements
October 2006



Who is supporting the Single Dose



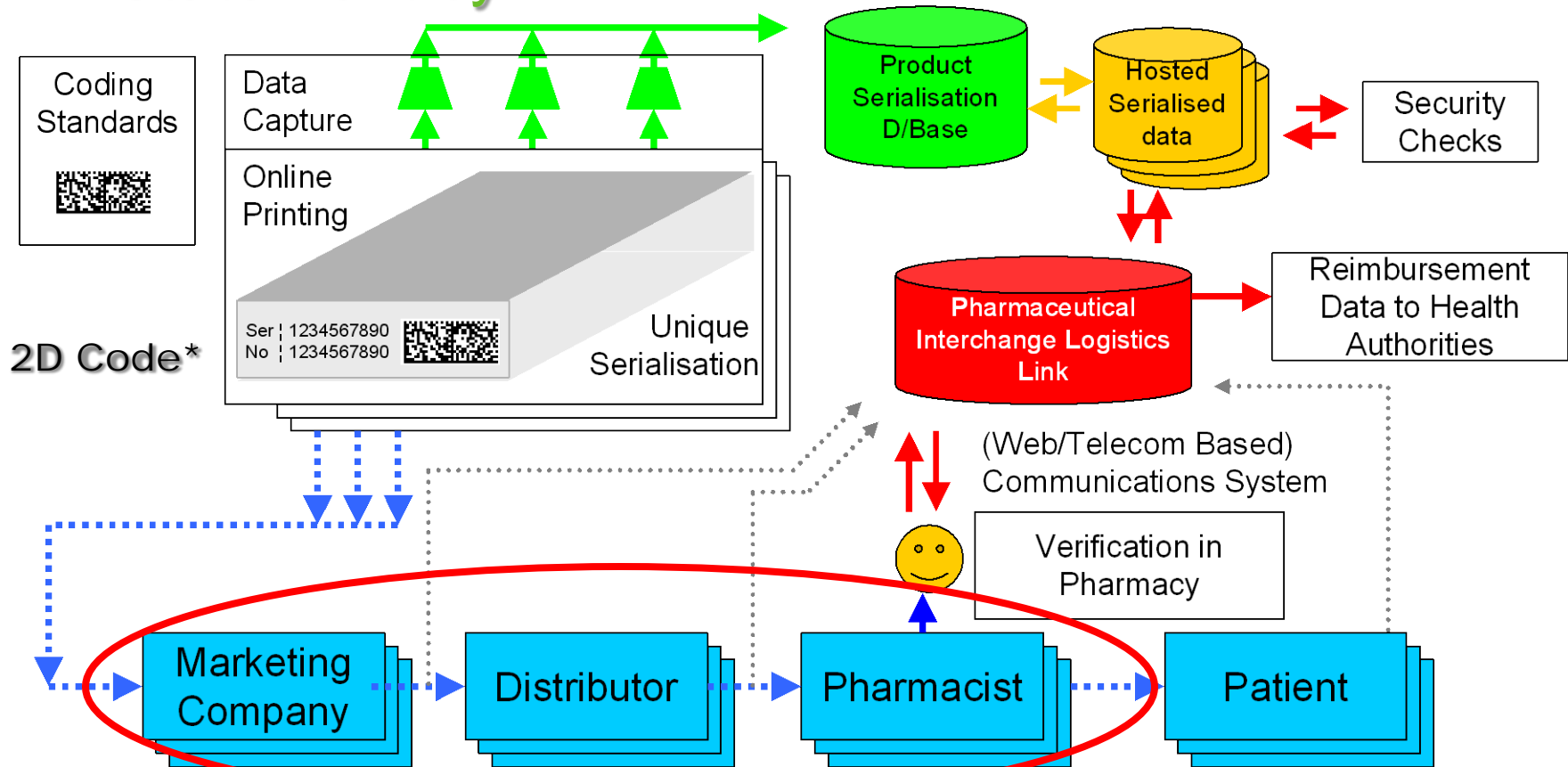
- **Pharmaceutical industry**

Statement by EFPIA (fighting counterfeit)
October 2009

*“EFPIA calls for the introduction of a harmonised coding solution in Europe, based on the two-dimensional barcode to **individually code each pack**”*



Statement by EFPIA



2D Code*

Coding Standards

Data Capture

Online Printing

Unique Serialisation

Ser | 1234567890
No | 1234567890

Product Serialisation D/Base

Hosted Serialised data

Security Checks

Pharmaceutical Interchange Logistics Link

Reimbursement Data to Health Authorities

(Web/Telecom Based) Communications System

Verification in Pharmacy

Marketing Company

Distributor

Pharmacist

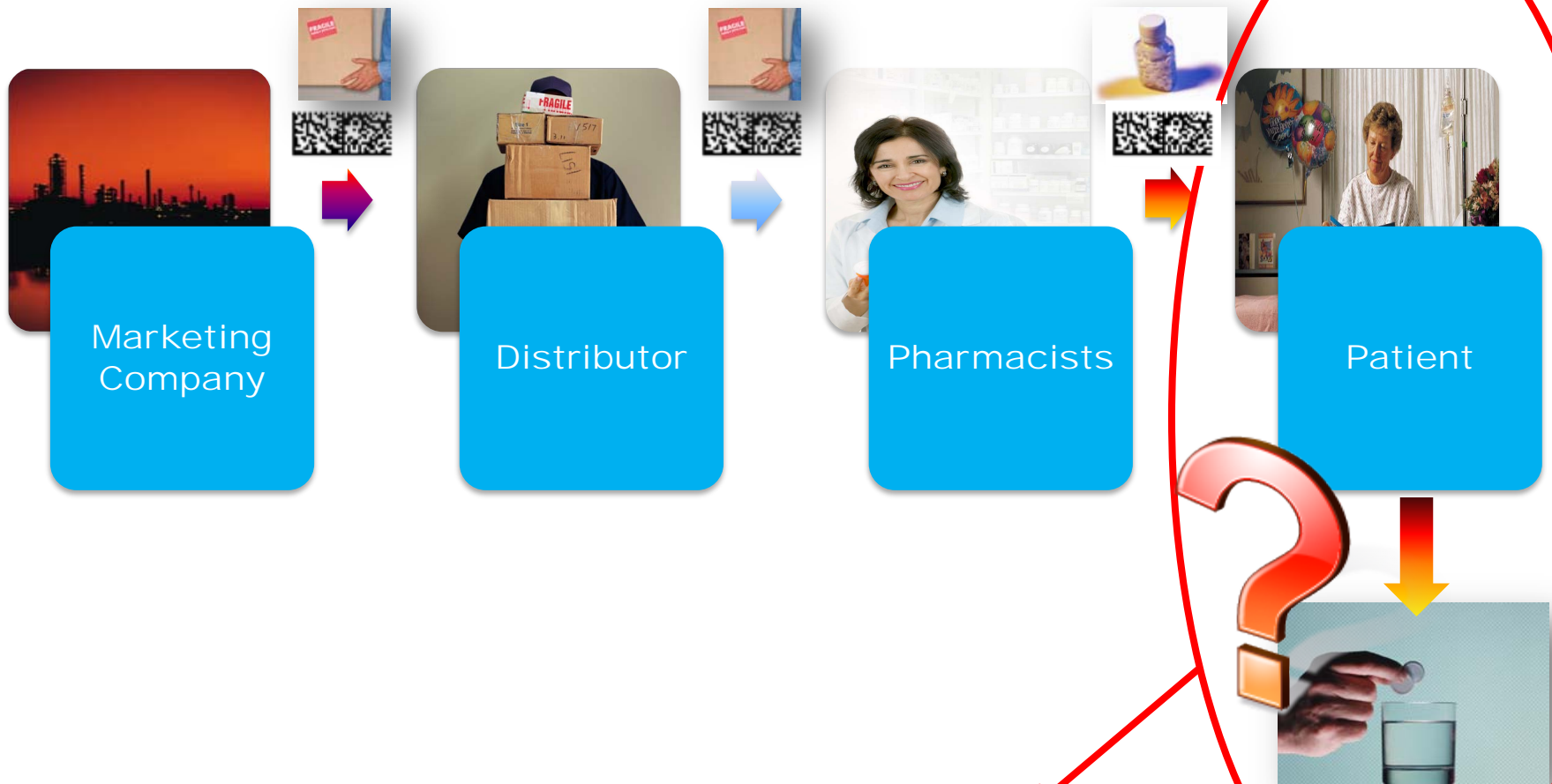
Patient

Focus on counterfeit

* 2D Datamatrix

- 1) Product/Manufacturer Code 14 digits [GTIN recommended]
- 2) Unique Serial Number 20 digits
- 3) Batch Number 10 alpha-numeric characters
- 4) Expiry Date 6 digits (yy/mm/dd)

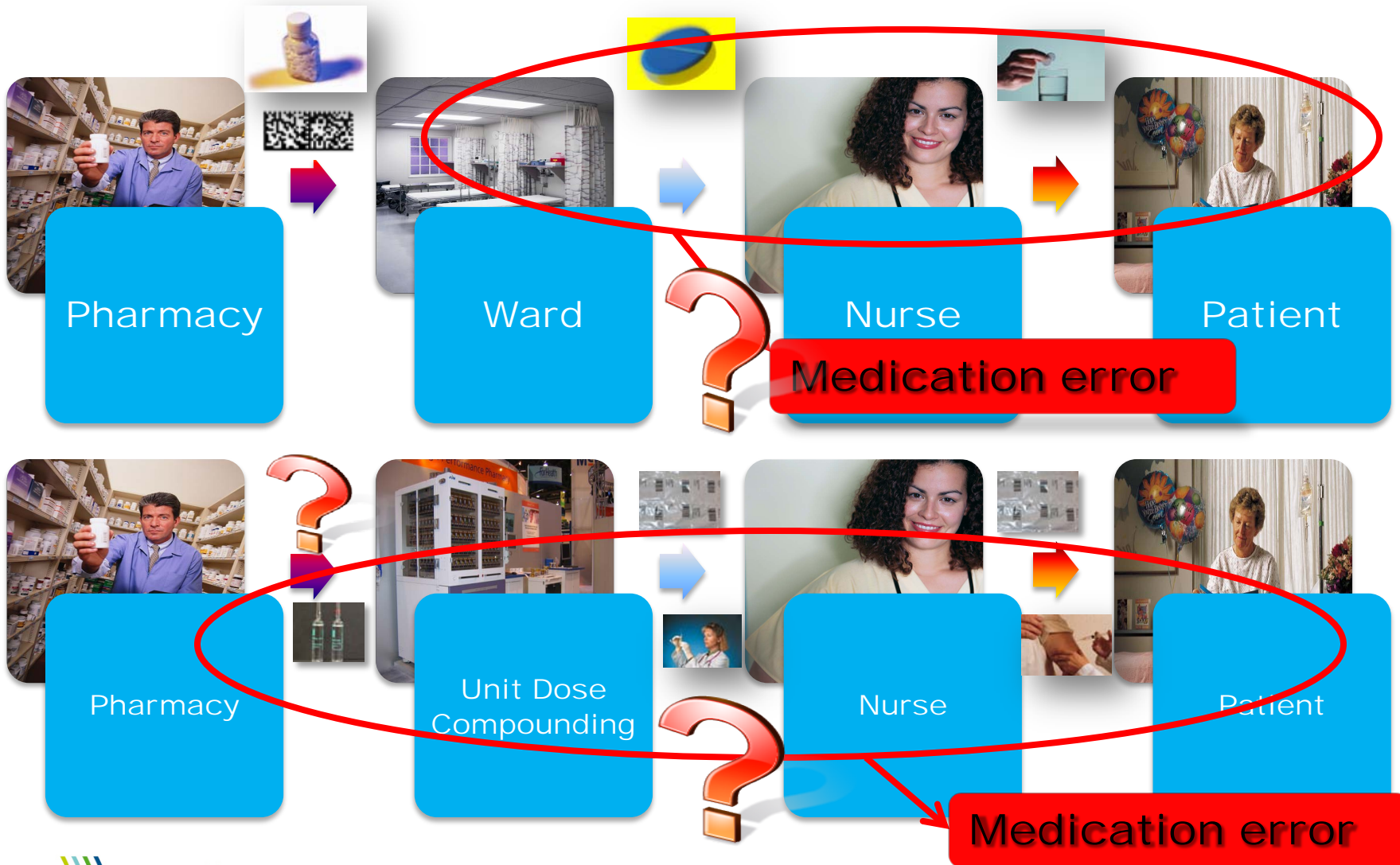
Medicines in the community pharmacy



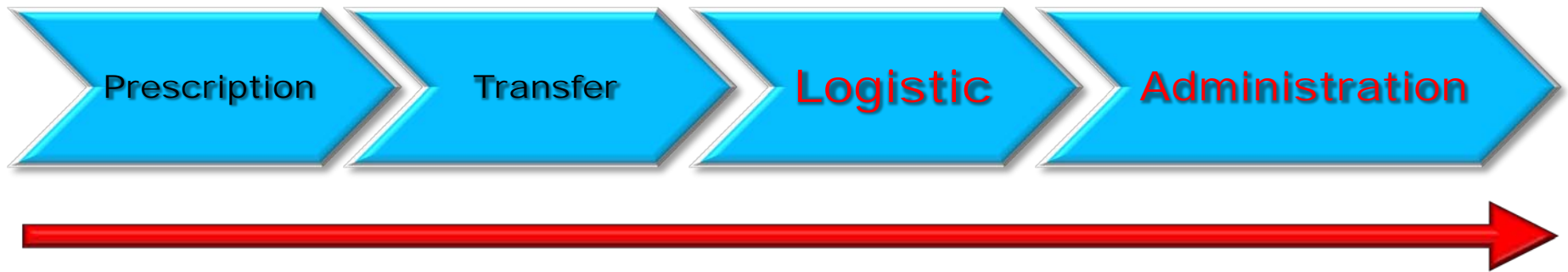
Focus on medication errors and patient safety



Medicines in hospitals



Medication errors



39%

12%

11%

38%

Why bar coded single dose in hospitals



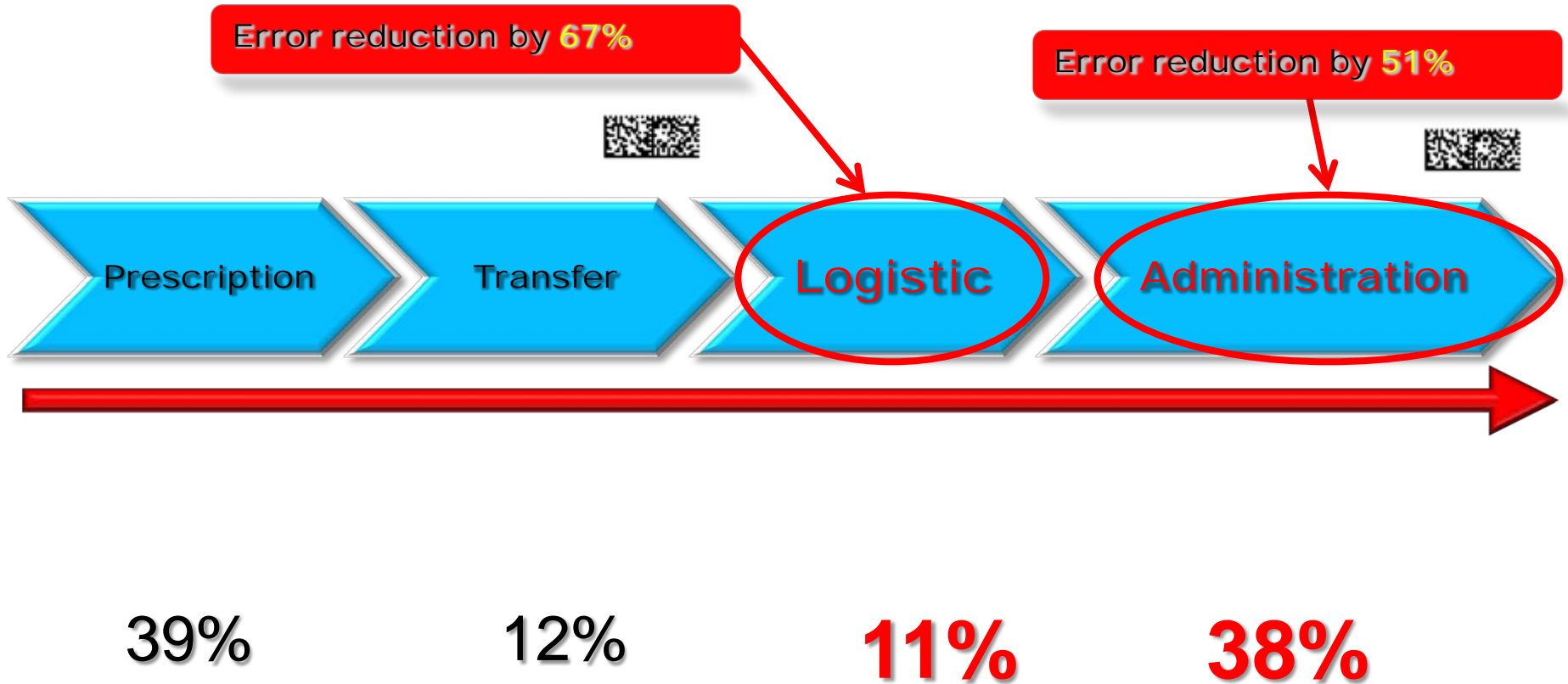
- To guarantee the permanent identification of a pharmaceutical product and secure its traceability within the hospital medication chain essentially **in order to prevent medication-related errors**
- **Barcode technology reduces errors by 41.4%** (11.5% \Rightarrow 6,8% absolutely)*
- i.e. every 21st patient will have a benefit (NNT** = 21)



* Poon EG et al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Eng J Med 2010;362:1698-707

** NNT = Number Needed to Treat

Medication errors: effect of bar-coding



Poon EG et al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Eng J Med 2010;362:1698-707

Why bar coded single dose in hospitals



- **To avoid mis-reading and understanding of labels**
 - There is no common technology to read the product information by means of technical equipment and therefore no homogeneity, neither from manufacturer to manufacturer, nor from country to country



Why bar coded single dose in hospitals



- **To alert faster and better on potential interactions**
- **To avoid risk of degradation of medical products form bulk containers (without packaging) because they could be sensitive to moisture, light or temperature**




Why bar coded single dose in hospitals



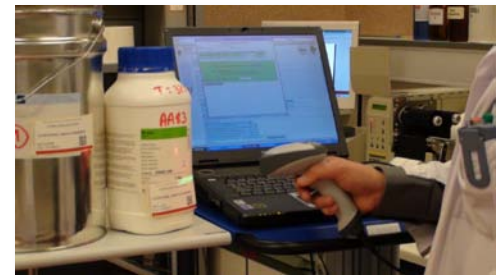
- **to protect children and help the elderly patients**
- **to reduce waste costs and raw material costs for repackaging in unite dose**
- **to reduce staff costs** (time spending on re-packaging and manually labelling)



Why bar code in hospitals

6-EL: REEDUC Madame 22.02.1990	
BLEOMYCINE 18,1 mg	INTRA VEINEUX J1
Seringue ad 6,03 ml	
Conservation: A température ambiante A l'abri de la lumière	Exp: 01.09.2009 à 08:00 Durée: h mn Posé le: à h Débit: ml/h
	Préparé le: 25.08.2009 à 08:00 Lot: D-cyt/09-4157
CHIMIOThERAPIE	

- To make the process of compounding and reconstitution more safe



Statement by EAHP update 2010



In hospitals, personalized treatments are prepared in the pharmacy or in the ward, and are administered by nurses to the patients.

A complete and unambiguous identification of the drug up until the moment of administration is a **key element of a safe dispensing procedure...**



Statement by EAHP update 2010



...when drugs are dispensed in multiple dose blisters, they have to be cut during drug dispensing, and, as a consequence, some information may be absent of the resulting dose and an accurate control at the bedside is no more feasible.



Statement by EAHP update 2010



A. The primary packaging of a medical product must fulfill 3 basic functions:

- precisely describe the content of the drug up to final control at bedside
- enable easy and safe use of the drug
- provide protection against environmental influences such as light, moisture, pressure and microbial contamination during transport, handling and storage.





B. Requirements for the single dose packaging

1. Size and form

- single dose packing for a single application, preferably in a standardized size (e.g. 3,5x3,5 cm)
- alternatively, perforated multiple dose blister packs that can be easily divided into single doses packing (each of them must contain the whole information)
- ready to use, no further manipulation necessary
- easy to pack into automatic dispensing systems.



Statement by EAHP update 2010



2. Information on the single doses

- The printing must be easy to read, durable and clear.
- Each single dose must contain the:
 - *trade name*
 - *application form*
 - *active substance(s)*
 - *quantity of active substance(s)*,
 - *manufacturer's name*
 - *expiry date*
 - *batch number*
 - barcode including the identification of the drug (**GTIN**), the expiry date and the batch number.

When the production facility is incompatible with an on-line printing of variable data, the barcode can **temporarily be limited to the identification of the drug**



Statement by EAHP update 2010



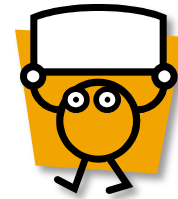
- Hospital pharmacists strongly recommend the use of a **recognized international standard, like the GS1** (ex- EAN) identification system for bar codes.
- The **GS1-128 (ex- EAN-128)** standard appears to be the best standard for the traceability of single dose units.
- Taking into account the problem of the available space, we recommend printing it as a bi- dimensional barcode (i.e. **datamatrix**).



- For ampoules and vials, the same information should be provided on a label (not engraved on the glass), with additional information regarding the
- Total amount and volume (x mg = y ml) and the concentration of the solution (z mg/ml).



Take home messages



- **The use of bar coded single dose reduces medication errors by 41.4% and is an important contribution to patient safety in hospitals**
- **EAHP requests the regulators to make bar coded single dose blisters mandatory for hospitals**
- **EAHP requests industry to pack all medicines for hospitals in bar coded single dose blisters**
- **The collaboration with industry is crucial to achieve this goal**



Thank you very much for your attention!

